Please add new Claim 34.

A5

34. (New) A method of Claim 23 wherein said media includes insulin.

REMARKS

The amendments to the Claims have been made to more particularly point out and distinctly claim the subject matter of the invention. Support for these amendments can be found, for example, at page 50, lines 11-17 as well as page 51, lines 1-15 of the specification.

Rejection of Claims 17-33 Under 35 U.S.C. § 112, second paragraph

Claims 17-33 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. It was stated that Claims 17 and 23 recite the inclusion of potassium, calcium and magnesium in the solution, whereas these substances are probably intended to be ions rather than metals as inferable from the claim language. It was stated that the term "agent" was misspelled in Claims 18 and 25. Finally, it was stated that there is a redundancy in using "glucose" and "dextrose" as alternatives in Claim 21.

Claims 17, 18, 21, 23, and 25 have been amended with the present amendment to address the concerns raised by the Examiner. Applicant appreciates the pointing out of these oversights in the initial claims by the Examiner.

Rejection of Claims 17, 18, 21, and 22 Under 35 U.S.C. § 102(b)

Claims 17, 18, 21, and 22 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Turpin *et al.* in view of Dobrian *et al.* or Birkett *et al.* or Watanabe *et al.* Although this rejection was stated as an anticipation rejection under 35 U.S.C. § 102(b), it is believed by Applicant that the Examiner meant to reject Claim 17 under 35 U.S.C. § 102(b) as being anticipated by Turpin *et al.*, and dependent Claims 18, 21, and 22 under 35 U.S.C. § 103(a) as being unpatentable over Turpin *et al.* in view of Dobrian *et al* or Birkett *et al.* or Watanabe *et*

al. Applicant will assume this was the intention of the Examiner in the following discussion of this rejection.

It was stated that Turpin *et al.* discloses a composition comprising Krebs-Ringer bicarbonate buffer with 1.5% albumin at pH 7.4 to which has been added 0.3 μM epinephrine plus adenosine 0.1 μM. It was further stated that albumin is a cytoprotective agent as demonstrated by its antioxidative properties (Dobrian *et al.*) and is well known to have fatty acids and steroids associated with it (Birkett *et al.* and Watanabe *et al.*). It was concluded that the composition of Turpin *et al.* which comprises albumin would also contain antioxidant, steroid and fatty acid since albumin preparations contain steroid and fatty acid and exhibit antioxidative properties.

Turpin *et al.* shows a buffer solution containing Krebs-Ringer substances and bovine serum albumin at pH 7.4 (see page 443, left column, third full paragraph). To this buffer solution is added epinephrine and adenosine during experimental procedures (e.g., see page 444, Figure 4). However, it should be noted that the bovine serum albumin shown in this reference lacks fatty acids (see page 443, left column, second full paragraph). This was purposefully done because the fatty acids interfere with experimental design of the study of the reference. It was indicated by the authors that fatty acids probably do not accumulate in their media (see page 447, left column, last full paragraph).

The organ preservation solution of presently amended independent Claim 17 contains at least one fatty acid. The solutions of Turpin *et al.* do not contain fatty acids, particularly in the free state. Thus, present Claim 17 is not anticipated by Turpin *et al.* The teachings of Dobrian *et al.*, Birkett *et al.* and Watanabe *et al.* do not cure this defect in the teachings of Turpin *et al.* because these three references do not discuss buffer solutions such as those of Turpin *et al.* but, instead, merely show certain properties of commercial albumin. The fatty acid content of albumin shown by Birkett *et al.* is negated by the lack of fatty acids associated with the bovine serum albumin of Turpin *et al.* There is an articulated disparity between the teachings of Turpin *et al.* and Birkett *et al.*

Therefore, it is believed by Applicant that the present Claims are free of the prior art.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (978) 341-0036.

Respectfully submitted,

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MARKED UP VERSION OF AMENDMENTS

Claim Amendments Under 37 C.F.R. § 1.121(c)(1)(ii)

Replace Claims 17, 18, 21, 23, and 25 with the below Claims marked up by way of bracketing and underlining to show the changes relative to the previous versions of the Claims.

17. (Amended) An organ preservation solution for the preservation of a human or human-compatible harvested organ in a functioning state comprising:

(1) a metabolizable carbohydrate;

(2) sodium chloride;

(3) potassium ion;

(4) calcium ion;

(4) magnesium ion;

(6) bicarbonate ion;

(7) epinephrin; [and]

(8) adenosine; and

(9) at least one fatty acid;

wherein said solution is substantially free of [a] non metabolizable impermeants; and further wherein said solution has a pH of about 7.4 to about 8.5.

18. (Amended) A solution according to Claim 17 wherein said solution further comprises a pharmaceutically active agent selected from the group consisting of heparin, nitroglycerin, an ACE inhibitor, a beta blocker, a calcium channel blocker, a cytoprotective agent, an antioxidant, an anti-fungal agent, an anti-viral agent, an anti-bacterial agent, an immunosuppressive agent, a nonsteroidal anti-inflammatory agent, a steroid , vitamins and mixtures thereof.

21. (Amended) A solution according to Claim 18 wherein said metabolizable carbohydrate is [selected from the group consisting of dextrose,] glucose[, and mixtures thereof].

23. (Amended) A method of preserving a human or human-compatible harvested organ in a functioning state during a preservation period prior to implantation comprising:

(a) providing an organ in need of preservation;

(b) providing containment means for said organ;

(c) providing a preservation fluid media; said fluid media comprising:

(i) whole blood or leukocyte-depleted whole blood that is compatible with said organ; and

(ii) a preservation solution comprising:

(a) a metabolizable carbohydrate;

(b) sodium chloride;

(c) potassium ion;

(d) calcium ion;

(e) magnesium ion;

(f) bicarbonate; epinephrin; and [insulin] adenosine;

(d) delivering said fluid media to at least one major vessel of said contained functioning organ while said organ is maintained at a normothermic temperature of about 20° C. to about 37° C.

25. (Amended) A method according to Claim 23 wherein said media further includes a pharmaceutically active agent selected from the group consisting of nitroglycerin, an ACE inhibitor, a beta blocker, a calcium channel blocker, a cytoprotective agent, an antioxidant, an anti-fungal agent, an anti-viral agent, an anti-bacterial agent, an immunosuppressive agent, a nonsteroidal anti-inflammatory agent, a steroid, and mixtures thereof.